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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,608	03/15/2004	Stephen Truesdale Carney		1797

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,608	CARNEY, STEPHEN TRUESDALE	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 13-25 are pending in the application and were examined on their merits.

Claim Objections

Claims 15-18 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim. Specifically, claims 13-18 are dependant upon claims '13 and 14'. This should properly read '13 or 14'. See MPEP § 608.01(n). Typically, these claims are not further examined on the merits. However, since it is not a burden of search, the claims were examined on their merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-14 and 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Rink, L (2/2003).

Rink, L. (2/2003) disclosed the study as found in the Instant specification more than one year prior to Applicant's earliest effective filing date.

Specifically, Rink, L. disclosed a method for decreasing LDL, increasing HDL, decreasing C-reactive protein, homocysteine and triglycerides with a capsules comprising 560mg of alfalfa sprout powder and 460mcg of folic acid, wherein either two capsules were taken once per day, or wherein two capsules were taken twice per day (see entire reference, especially page 2 and results on pages 1 and 3). It is noted that claim 21 states 'occurs once during a twenty-four hour period' is anticipated by Rink in that the claim is an open claim. Therefore, the administration occurred once, and then it occurred again, since the capsules were administered twice in a day. Because the claim does not state 'only once a day', the method disclosed by Rink anticipates this claim. Consequently, the phrase 'occurs at least twice during a twenty-four hour period' is also anticipated because it is evident from Group C that two tablets were administered twice a day (p. 2). Further, a capsule form of a composition is a 'delayed release' form because the capsule needs to dissolve prior to release of the drug. Also, a powder is considered a 'microparticle' (claim 20).

Claims 13-14 and 18-21 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Muldoon, K. (1996).

Muldoon, K. (1996) reporting for The Oregonian, indicated that a Mr. H. Kahalsa ingested alfalfa powder along with a banana every morning (see entire article, especially page 2). Bananas naturally contain vitamin C. It is deemed that lowering of LDL, C Reactive protein, triglycerides and Homocysteine levels as well as increasing HDL must have been an inherent consequence of ingesting the alfalfa powder, and/or the alfalfa powder mixed with banana. The reference is deemed anticipated because the only step in the method of the claims is administering an effective amount. The term 'effective amount' is not defined in the Instant specification. Thus, the term 'effective amount' is rendered very broad. It is deemed that this amount is drawn to any amount. Further, it is deemed that because the alfalfa powder inherently possesses these abilities, that small amounts would be at least somewhat effective, especially absent evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-14 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rink, L. (2/2003).

The teachings of Rink, L. were discussed *supra*. Rink did not specifically teach wherein indicia was included with the capsules.

Although the prior art did not specifically state where written instructions were given on how to take the capsules, it is deemed that one of ordinary skill in the art would have been motivated to provide indicia to indicate the time period for administration to help the patient remember when to take their medication in order to improve the outcome of treatment. "Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. In re Ngai, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004) (MPEP §2112.01). Although the Instant claims are method claims, it follows from *In re Ngai* that instructions do not

change the overall method in that it is clear that the study participants were instructed with regard to how to take the capsules which is an obvious variation of a written form of the same instructions.

Claims 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rink, L. (2/2003) in view of Boulos et al. (2002/0172721).

The teachings of Rink, L. were discussed *supra*. Rink, L. did not specifically teach wherein vitamins B12 and B6 were added into the composition. Rink did however, specifically state that vitamins B12 and B6 possibly lowered homocysteine levels and thus lowered C-reactive proteins (see p. 2).

Boulos et al. (2002/0172721) teach a composition for treatment of cardiovascular diseases which beneficially include folic acid , vitamin B6 in an amount of about 2 to 200 mg and B12 at an amount of about 10 to about 600 micrograms for administration to persons having low HDL and high LDL (see entire reference, especially [0005] [0017] and [0051]).

Boulos et al. specifically state :

> Folic Acid is a B complex vitamin. It is water-soluble and occurs naturally in green plants, fresh fruit, and yeast. Folic acid along with Vitamins B.sub.12 (cyanocobalamin) and B6 play a key part in homocysteine metabolism... It has been suggested that a 5 .mu.mole/L increment in homocysteine level confers a relative increase in risk of coronary heart disease of 1.6 for men, and 1.8 for women [0025]

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). See MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations of vitamins B6 and B12 because these vitamins are considered art-recognized result-effective variables which would have been routinely determined and optimized in the pharmaceutical art. Vitamins B6 and B12 are clearly result-effective, in that they were known in the art for affecting homocysteine levels as described by Boulos et al. Boulos et al. further disclosed desired amounts of Vitamins B6 and B12 which were advantageous. Although Boulos et al. did not disclose the particular amounts of these vitamins as Instantly claimed, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature. Although the prior art does not teach the amounts of Vitamins B6 and B12 as Instantly claimed, it would be conventional and within the skill of the art to identify the optional concentrations of the vitamins because the selection of appropriate concentration of vitamins B6 and B12 in order to provide a positive effect in individuals of different weights/age/health condition would have been obvious to one of ordinary skill in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

The prior art of record as listed on the PTO-892 form and not relied upon is considered pertinent to Applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

May 3, 2007